

PATENT COOPERATION TREATY

T.-ART / FRIST

claims amended
21.03.05

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: ZLB BEHRING GMBH Patents & Licences Postfach 1230 D-35002 Marburg GERMANY	ZLB Behring GmbH Patents and Licences Abl.: 2003/4014 Wv.: 24. Jan. 2005 Erh.:	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION (PCT Rule 44.1)
Applicant's or agent's file reference	Date of mailing (day/month/year) 21/01/2005 FOR FURTHER ACTION See paragraphs 1 and 4 below	
International application No. PCT/EP2004/009085	International filing date (day/month/year) 13/08/2004	
Applicant ZLB BEHRING GMBH		

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders


Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Eva Boháčová
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/009085

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K38/57 A61P31/12 A61P31/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, EMBASE, CHEM ABS Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 969 017 A (CENTEON PHARMA GMBH) 5 January 2000 (2000-01-05) column 1, lines 27-30 column 2, line 48 - column 3, line 29 -----	1,2,5,6
X	US 6 242 239 B1 (GROENER ALBRECHT ET AL) 5 June 2001 (2001-06-05) abstract; claims 1,2 -----	1,2,5,6
X	KIRSCHFINK M ET AL: "C1-INHIBITOR: AN ANTI-INFLAMMATORY REAGENT WITH THERAPEUTIC POTENTIAL" EXPERT OPINION ON PHARMACOTHERAPY, ASHLEY, LONDON,, GB, vol. 2, no. 7, 2001, pages 1073-1083, XP009007955 ISSN: 1465-6566 abstract ----- -/-	6

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the International filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the International filing date but later than the priority date claimed

T later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the International search

14 December 2004

Date of mailing of the International search report

21/01/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Escolar Blasco, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP2004/009085

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DROUET CHRISTIAN ET AL: "Hepatitis C virus NS3 serine protease interacts with the serpin C1 inhibitor" FEBS LETTERS, vol. 458, no. 3, 24 September 1999 (1999-09-24), pages 415-418, XP002310593 ISSN: 0014-5793 page 418, left-hand column, paragraph 3 page 415, right-hand column, lines 4,5, paragraph 4</p> <p>-----</p>	1,2,6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/009085

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0969017	A	05-01-2000	DE 19829014 A1	05-01-2000
			AU 766767 B2	23-10-2003
			AU 3686599 A	13-01-2000
			CA 2276564 A1	30-12-1999
			EP 0969017 A1	05-01-2000
			JP 2000044599 A	15-02-2000
			KR 2000006553 A	25-01-2000
			US 2004152635 A1	05-08-2004
US 6242239	B1	05-06-2001	DE 19827750 C1	29-07-1999
			AU 745851 B2	11-04-2002
			AU 3578199 A	06-01-2000
			CA 2276785 A1	23-12-1999
			EP 0966976 A1	29-12-1999
			JP 2000032978 A	02-02-2000
			KR 2000006313 A	25-01-2000
			US 2004152635 A1	05-08-2004

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, Item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)	
PCT/EP2004/009085	13/08/2004	19/08/2003	
Applicant ZLB BEHRING GMBH			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/009085

International filing date (day/month/year)
13.08.2004

Priority date (day/month/year)
19.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K38/57, A61P31/12, A61P31/16

Applicant
ZLB BEHRING GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Escolar Blasco, P

Telephone No. +49 89 2399-7331



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/009085

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/009085

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,4
	No: Claims	1,2,5,6
Inventive step (IS)	Yes: Claims	3,4
	No: Claims	1,2,5,6
Industrial applicability (IA)	Yes: Claims	1-6
	No: Claims	

2. Citations and explanations

see separate sheet

Comments on item V

1. The documents cited in the International Search Report correspond respectively to D1-D4. Any reference to the documents in the present written opinion relates to the passages given in said report, unless otherwise indicated.

D1: EP-A-0 969 017

D2: US-B-6 242 2391

D3: KIRSCHFINK M ET AL: "C1-INHIBITOR: AN ANTI-INFLAMMATORY REAGENT WITH THERAPEUTIC POTENTIAL" EXPERT OPINION ON PHARMACOTHERAPY, ASHLEY, LONDON,, GB, vol. 2, no. 7, 2001, pages 1073-1083

D4: DROUET CHRISTIAN ET AL: "Hepatitis C virus NS3 serine protease interacts with the serpin C1 inhibitor" FEBS LETTERS, vol. 458, no. 3, 24 September 1999, pages 415-418

2. The use of C1-inh for neutralization of pathogenic viruses with membrane constituents having acceptor functions is known in the art, since D1 and D2 disclose the binding of C1-inh to HIV and D4 to HCV. These documents anticipate the subject-matter of claims 1, 2 and 6.
 - 2.1 Concerning claim 6, please note that it is construed as encompassing the use of C1-inh as therapeutic or diagnostic agent. The mechanism of action given (neuraminidase inhibitor) is not limiting the scope of the claim. Any previous medical use of C1-inh (like D3) is thus novelty destroying for claim 6.
 - 2.2 D2 discloses also a method for separating HIV viruses from fluids, which is based on the binding of the virus to C1-inh. This document anticipates also the subject-matter of claim 5.
3. The interaction of C1-inh with haemagglutinin is neither disclosed nor suggested in any of the available documents. Hence, the subject-matter of claims 3 and 4 is considered to be novel and inventive.